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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,188	09/17/2003	Satoru Iguchi	PC25301A	8576
28523	7590	01/21/2005	EXAMINER	
PFIZER INC. PATENT DEPARTMENT, MS8260-1611 EASTERN POINT ROAD GROTON, CT 06340			HUANG, EVELYN MEI	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 01/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/667,188	IGUCHI ET AL.	
	Examiner	Art Unit	
	Evelyn Huang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 13-20 are pending. Claims 1-12 have been canceled according to the amendment filed on 10-25-2005.

Claim Rejections - 35 USC § 112

2. The cancellation of Claim 11 has rendered moot the rejection under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. However, new claims 19-20 are subjected to the written description rejection for the following reasons.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. A full description of the inventive compound as agonists and/or antagonists of the 5-HT₄ receptors is not found in the specification. The instant method for agonizing 5-HT₄ receptors or antagonizing the 5-HT₄ receptors reaches out to as yet unidentified diseases/conditions/activities, the description of which is not found in the specification.

Claim Rejections - 35 USC § 112(1)

3. The rejection for Claims 10-12 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is rendered moot by the cancellation of these claims. However, new claims 10-20 are subjected to the enablement rejection for the following reasons.

Biological pathways by themselves are devoid of identifiable utility and are therefore not useful. Unless the pathway at issue is critical to treating some condition and the pathway modification and disease treatment are inexorably linked, such pathway modification is devoid of utility. The instant claim directed to a mechanism of agonizing or antagonizing 5-HT₄ receptors without the end result would therefore have no practical utility unless the agonism or antagonism of 5-HT₄ receptors and treatment of diseases are inexorably linked.

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At the time of the invention, a nexus between the activation or inhibition of 5-HT₄ receptors and the treatment or prevention of any or all of the recited diseases have not been fully established (Barnes et al. Neuropharmacology 38(1999) 1083-1185, 1118-1125). Furthermore, since the claims as recited embrace any degree of agonizing or antagonizing 5-HT₄ receptors, which may or may not inexorably linked to the treatment of any or all the diseases recited, the scope of the claims therefore does not commensurate with that of the objective enablement, especially in view of the absence of a full written description of the as yet unidentified conditions/activities/disorders which the recited mechanism reaches out to. One of ordinary skill in the art therefore would not be able to use the inventive compound as claimed without undue experimentation.

Claim Rejections - 35 USC § 102

4. The rejection for Claims 1-12 under 35 U.S.C. 102(e) as being anticipated by Uchida (6624162) is rendered moot by the cancellation of these claims.

Double Patenting

5. The rejection for Claims 1-12 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 8-11 of U.S. Patent No. 6624162 is rendered moot by the cancellation of these claims.

6. The provisional rejection for claims 1-12 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the corresponding claims of copending Application No. 10/617920 (division of 6624162) is rendered moot by the cancellation of these claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchida (6624162, with an effective filing date of 10-2-2001, and is available as prior art under 102(e)).

Uchida generically discloses and claims a 5-HT₄ receptor binding compound, its composition and method of use (claims 1-5, 8-11). Specific compounds are described and claimed (claims 6-7).

The compound of Uchida's claim 6 has a butyl whereas the compound of instant claim 17 has an isobutyl as R₃ (corresponding Uchida's R₆).

Butyl and isobutyl, however, are optional choices within the C₁₋₅ alkyl of R₆ (column 54, claim 5, line 24; definition of alkyl is found on column 3, lines 17-20, wherein butyl and isobutyl are expressly described).

At the time of the invention, one of ordinary skill in the art would be motivated to replace Uchida's butyl with the alternative isobutyl to arrive at the instant invention, with the reasonable expectation of obtaining an additional compound with 5HT₄ binding activity, since Uchida had expressly taught that any species within the disclosed genus, especially the preferred genus, would be an effective 5HT₄ ligand.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6624162. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Uchida generically discloses and claims a 5-HT₄ receptor binding compound, its composition and method of use (claims 1-5, 8-11). Specific compounds are described and claimed (claims 6-7).

The compound of Uchida's claim 6 has a butyl whereas the compound of instant claim 17 has an isobutyl as R₃ (corresponding Uchida's R₆).

Butyl and isobutyl, however, are optional choices within the C₁₋₅ alkyl of R₆ (column 54, claim 5, line 24; definition of alkyl is found on column 3, lines 17-20, wherein butyl and isobutyl are expressly described).

At the time of the invention, one of ordinary skill in the art would be motivated to replace Uchida's butyl with the alternative isobutyl within the C₁₋₅ alkyl to arrive at the instant invention, with the reasonable expectation of obtaining an additional compound with 5HT₄ binding activity, since Uchida had expressly taught that any species within the disclosed genus, especially the preferred genus, would be an effective 5HT₄ ligand.

9. Claims 13-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/617920 (division of 6624162). Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons set forth in the preceding paragraph.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

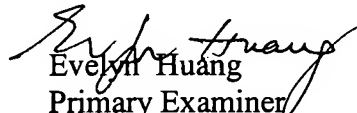
Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Evelyn Huang
Primary Examiner
Art Unit 1625